UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5

In the Matter of:	)	
	)	
BEHNKE LUBRICANTS, INC.	)	**COMPLAINANT'S THIRD**
MENOMONEE FALLS, WISCONSIN	)	**SUPPLEMENTAL PREHEARING**
	)	**EXCHANGE**
	)	
Respondent.	)	
	)	**Docket No. FIFRA-05-2007-0025**

COMPLAINANT'S THIRD SUPPLEMENTAL PREHEARING EXCHANGE

Complainant, Region 5, United States Environmental Protection Agency (U.S. EPA), through its undersigned attorneys, hereby files the instant Complainant's Third Supplemental Prehearing Exchange pursuant to Section 22.19 of the *Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits* (Consolidated Rules), codified at 40 C.F.R. § 22.19.

I. Additional Exhibits

Complainant is moving to supplement its Prehearing Exchange to add the following exhibits:

CX 65	FDA Consumer Magazine, Bacteria Eating Virus Approved as Food Additive, January-February 2007, *available at* www.fda.gov/fdac/features/2007/107_virus.html
CX 66	FDA/IFIC Brochure, Food Additives, January 1992, *available at* vm.cfsan.fda.gov/~lrd/foodaddi.html
CX 67	USDA, Guidance on Ingredients and Sources of Radiation Used to Reduce Microorganisms on Carcasses, Ground Beef, and Beef Trimmings, *available at* www.fsis.usda.gov/OPPDE/rdad/FRPubs/00-022N/IngredGuid.htm

CX 68 FDA, Food Ingredients and Packaging Terms, *available at* www.cfsan.fda.gov/~dms/opa-def.html

Complainant's Second Motion to Supplemental Prehearing Exchange is being filed contemporaneously with the instant filing.

II. Reservation of Rights

Complainant respectfully reserves the right to supplement its list of witnesses and/or its list of exhibits upon reasonable notice to Respondent, or by order of this Honorable Court.

Complainant's Third Supplemental Prehearing Exchange for *In the Matter of Behnke Lubricants, Inc.*, is hereby respectfully submitted.

Respectfully Submitted,

/s/ 2/27/08

Nidhi K. O'Meara Date
James J. Cha
Erik H. Olson
Associate Regional Counsels
U.S. EPA, Region 5

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
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In the Matter of:	)	
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BEHNKE LUBRICANTS, INC.	)	**COMPLAINANT'S MOTION TO**
MENOMONEE FALLS, WISCONSIN	)	**SUPPLEMENT PREHEARING**
	)	**EXCHANGE**
	)	
	)	**Docket No. FIFRA-05-2007-0025**
Respondent.	)	

COMPLAINANT'S MOTION TO SUPPLEMENT PREHEARING EXCHANGE

By the instant motion, Complainant, Region 5, United States Environmental Protection Agency (U.S. EPA), through its undersigned attorneys, moves to supplement its Prehearing Exchange pursuant to Sections 22.16(a) and 22.19(f) of the Consolidated Rules of Practice Governing the Administrative Assessment of Civil Penalties, Issuance of Compliance or Corrective Action Orders, and the Revocation, Termination or Suspension of Permits ("Consolidated Rules"), codified at 40 C.F.R. §§ 22.16(a) and 22.19(f). Complainant moves the Presiding Administrative Law Judge to allow Complainant to add the additional exhibits identified below to its Prehearing Exchange.

Background

On February 21, 2008, Respondent filed its Response to Complainant's Motion for Accelerated Decision on Liability and on Affirmative Defenses (Response). In its Response, Respondent argued, among other things, that its lubricants are "food additives" under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. Response, p. 23. Complainant wishes to supplement its Prehearing Exchange with the four exhibits described below solely to respond to the "food additive" arguments raised

by Respondent in the Response. Complainant refers to two of the four subject exhibits in its Reply to Respondent's Response to Complainant's Motion for Accelerated Decision on Liability and on Affirmative Defenses, which is filed contemporaneously with this Motion. Complainant may refer to all four of the subject exhibits at hearing should this Motion to Supplement be granted and should Complainant's Exhibits (CX) 65, 66, 67, and 68 be entered into evidence at hearing. CX 65, 66, 67, and 68 are all items of documentary evidence published or posted by the United States Food and Drug Administration (FDA) and United States Department of Agriculture (USDA) as guidance or informational articles that discuss or define the term "food additive."

Complainant hereby moves to supplement its Prehearing Exchange to add the following exhibits:

CX 65	FDA Consumer Magazine, Bacteria Eating Virus Approved as Food Additive, January-February 2007, *available at* www.fda.gov/fdac/features/2007/107_virus.html
CX 66	FDA/IFIC Brochure, Food Additives, January 1992, *available at* vm.cfsan.fda.gov/~lrd/foodaddi.html
CX 67	USDA, Guidance on Ingredients and Sources of Radiation Used to Reduce Microorganisms on Carcasses, Ground Beef, and Beef Trimmings, *available at* www.fsis.usda.gov/OPPDE/rdad/FRPubs/00-022N/IngredGuid.htm
CX 68	FDA, Food Ingredients and Packaging Terms, *available at* www.cfsan.fda.gov/~dms/opa-def.html

Complainant's Third Supplemental Prehearing Exchange is being filed contemporaneously with this motion.

Governing Legal Standard

The regulation governing supplementation of prehearing exchanges is found at 40 C.F.R. § 22.19(f), which provides as follows:

> (f) Supplementing prior exchanges. A party who has made an information exchange under paragraph (a) of this section [22.19], ... shall promptly supplement or correct the exchange when the party learns that the information exchanged ... is incomplete, inaccurate or outdated, and the additional or corrective information has not otherwise been disclosed to the other party pursuant to this section.

In addition, the rules on the admission of evidence that govern administrative hearings under the Consolidated Rules allow for supplementation of prehearing exchanges at least fifteen days prior to the scheduled hearing, subject to the discretion of the Presiding Administrative Law Judge. The rule at 40 C.F.R. § 22.22(a)(1) provides that "[t]he Presiding Officer shall admit all evidence which is not irrelevant, immaterial, unduly repetitious, unreliable, of little probative value, ... If, however, a party fails to provide any document, exhibit, witness name or summary of expected testimony required to be exchanges under § 22.19(a), (e) or (f) to all parties at least 15 days before the hearing date, the Presiding Officer shall not admit the document, exhibit or testimony into evidence, unless the non-exchanging party had good cause for failing to exchange the required information and provided the required information to all other parties as soon as it had control of the information, or had good cause for not doing so." In essence, this regulation embodies a policy favoring the admission of all relevant and material evidence, and only prohibits the inclusion of such evidence if it has not been provided to all parties at least 15 days prior to the hearing.

Timeliness of Motion to Supplement Prehearing Exchange, and Absence of Prejudice to Respondent

In the case at bar, Complainant is supplying the additional evidence more than a month from the date of hearing. The new exhibits are being offered solely to respond to arguments that Respondent advanced for the first time in its response to Complainant's Motion for Accelerated Decision. The additional evidence is being delivered to Respondent's counsel by Federal Express on the date of filing of this motion. Hence, the exhibits in Complainant's proposed supplement to its Prehearing Exchange are being provided to Respondent and to the Court well in advance of the hearing, and clearly within the time frame established by 40 C.F.R. § 22.22(a)(1). Additionally, all of the documents are less than nine pages long, and will therefore not be a burden for Respondent to review.

Prior decisions by the Environmental Appeals Board support the inclusion of this evidence in the record. *See, e.g., In re: CDT Landfill Corp.*, 11 E.A.D. 88, at 109-10 (EAB 2003) (holding that ALJ's decision to admit document relevant to issue of respondent's ability to pay, which document had been provided to opposing party only nine days prior to the hearing date, was not an abuse of discretion).[1]

Relevance and Materiality of the Additional Evidence

The additional exhibits are relevant and material to countering Respondent's argument that, because its products are "food additives" within the meaning of FDA regulations, those products are somehow exempt from FIFRA regulation. CX 65 – 68

[1] The Board observed that: "In light of the more relaxed rules in administrative hearings, together with the liberal standard of review for an ALJ's evidentiary determination, ... we are particularly wary of overruling an ALJ's decision when the issue raised concerns the ALJ's admission of evidence, as opposed to its exclusion. *Cf. Atlas Copco, Inc. v. EPA*, 642 F.2d at 467 (D.C. Cir. 1979) (stating that the discretion reposed in agencies to decide whether to admit particular evidence at a hearing is not unbridled and should not 'exclude from consideration facts and circumstances relevant to its inquiry' which 'may be persuasive weight in the exercise of its discretion')." 11 E.A.D. at 110

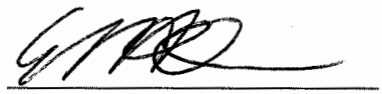
address the definition of the term "food additive,",the manner in which food additives must be approved by the FDA, and the different classes of food additives.

The exhibits covered by this motion will not introduce any new claims, nor will such evidence raise any new issues. Rather, the documents only support the existing claims, and address Respondent's defenses.

Conclusion

For all of the reasons set forth above, Complainant respectfully requests that this Honorable Court GRANT the instant *Complainant's Motion to Supplement Prehearing Exchange*.

Respectfully Submitted,



2/27/08

Nidhi K. O'Meara
James J. Cha
Erik H. Olson
Associate Regional Counsels
U.S. EPA, Region 5

Date

In the Matter of Behnke Lubricants, Inc.
Docket No. FIFRA-05-2007-0025

CERTIFICATE OF SERVICE

I hereby certify that the originals and true, accurate and complete copies of Complainant's Motion to Supplement Prehearing Exchange, and Complainant's Third Supplemental Prehearing Exchange, together with true, accurate and complete copies of Complainant's Exhibits 65-68, were filed with the Regional Hearing Clerk, U.S. EPA, Region 5, on the date indicated below, and that true, accurate and complete copies of Complainant's Motion to Supplemental Prehearing Exchange, Complainant's Third Supplemental Prehearing Exchange, and Complainant's Exhibits 65-68, were served on the Honorable Barbara Gunning, Administrative Law Judge (service by Pouch Mail), and Mr. Bruce McIlnay, Esq., Counsel for Respondent Behnke Lubricants, Inc. (service by Federal Express), on the date indicated below:

Dated in Chicago, Illinois, this 21 day of February, 2008.

Patricia Jeffries-Harwell
Legal Technician

Cx65

FDA Consumer magazine
January-February 2007

Bacteria-Eating Virus Approved as Food Additive

By Linda Bren

Not all viruses harm people. The Food and Drug Administration has approved a mixture of viruses as a food additive to protect people. The additive can be used in processing plants for spraying onto ready-to-eat meat and poultry products to protect consumers from the potentially life-threatening bacterium *Listeria monocytogenes* (*L. monocytogenes*).

The viruses used in the additive are known as bacteriophages. Bacteriophage means "bacteria eater." A bacteriophage, also called a phage (pronounced fayj), is any virus that infects bacteria.

Consuming food contaminated with the bacterium *L. monocytogenes* can cause an infectious disease, listeriosis, which is rarely serious in healthy adults and children, but can be severe and even deadly in pregnant women, newborns, older people, and people with weakened immune systems. Pregnant women are about 20 times more likely than other healthy adults to get listeriosis, according to the Centers for Disease Control and Prevention (CDC). Listeriosis can cause miscarriage, stillbirth, premature delivery, or death of a newborn baby.

People with listeriosis have fever and muscle aches, and sometimes an upset stomach, nausea, and diarrhea. If the infection spreads to the nervous system, headache, stiff neck, confusion, loss of balance, or convulsions can occur.

The CDC estimates that about 2,500 people become seriously ill with listeriosis each year in the United States. Of these, about 500 die.

Cooking can kill *L. monocytogenes*, but many ready-to-eat foods, such as hot dogs, sausages, luncheon meats, cold cuts, and other deli-style meats and poultry, may become contaminated within the processing plant after cooking and before packaging. Unlike fresh meat and poultry, the ready-to-eat products can be consumed without reheating, so the *L. monocytogenes* survive and are ingested.

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"*L. monocytogenes*can continue to thrive even in refrigerated conditions," says Capt. Andrew Zajac, a food safety expert and acting director of the Division of Petition Review within the FDA's Center for Food Safety and Applied Nutrition (CFSAN). "If a food product contaminated with *L. monocytogenes*is bought by a consumer and brought home and refrigerated, the bacteria can continue to multiply."

How Bacteriophages Work

Bacteriophages are found in the environment. "We're routinely exposed to bacteriophages," says Zajac. "They are found in soil and water, and they are part of the microbial population in the human gut and oral cavity."

Bacteriophages infect only bacteria, says Zajac. "They don't infect plant or mammalian cells." Thousands of varieties of phages exist, and each one infects only one type or a few types of bacteria. The particular phages approved as a food additive are very specific to *Listeria*, says Zajac. "They'll only thrive if *Listeria* are present."

The type of phage that was approved is lytic, which means that the phage destroys its host during its life cycle without integrating into the host genome. This type of phage works by attaching itself to a bacterium and injecting its genetic material into the cell. The phage takes over the metabolic machinery of the bacterium, forcing it to produce hundreds of new phages and causing the bacterial cell walls to break open. This process kills the bacterium and releases many new phages, which seek out other bacteria to invade and repeat the cycle.

"The process continues until all host bacteria have been destroyed," says Zajac. "Then the bacteriophages cease replicating. They need a host to multiply and will gradually become inactive when they lose the host."

Approval Process for Food Additives

To market a new food additive, a manufacturer must petition the FDA for its approval. The petition must provide convincing evidence that the proposed additive performs as it is intended and will not cause harmful effects when consumed.

If an additive is approved, the FDA issues a regulation that includes information on the types of foods in which the additive can be used and maximum amounts to be used. The regulation also provides the additive's identity and specifications on purity, which will ensure that the additive used in food is the same substance that was evaluated and approved by the FDA.

Once a food additive is approved, any company can use the additive, says Zajac, as long as it meets the conditions in the regulation.

In response to a petition submitted by industry, the FDA published a regulation in August 2006 permitting the use of a *Listeria*-specific bacteriophage preparation on ready-to-eat meat and poultry products.

The preparation combines six different phages that have been shown to be effective against 170 different strains of *L. monocytogenes*. Multiple phages are used so that if the *L. monocytogenes* develop resistance to several phages, the remaining ones can still destroy the bacteria.

The FDA must approve any additive before it can be used in food. When an additive is to be used on meat or poultry products, as with this one, both the FDA and the U.S. Department of Agriculture (USDA) are involved in the approval. The FDA evaluates the safety of the ingredient for its intended use. At the same time, the USDA evaluates the ingredient's suitability.

The FDA's food additive regulations define safety as "a reasonable certainty that the substance is not harmful under the intended conditions of use." The FDA's CFSAN determined that the phage preparation does not pose any safety concerns based, in part, on published reports submitted by the petitioner on the results of the use of phages in animal and human studies.

The USDA's Food Safety and Inspection Service (FSIS) evaluated the bacteriophage preparation's suitability. "Suitability establishes that the use of a substance is effective in performing the intended purpose of use and at the lowest level necessary for particular types of products," says Robert C. Post, Ph.D., director of the FSIS' Labeling and Consumer Protection Staff. In addition, suitability is an assurance that the use of the additive will not result in a product that is unfit for human consumption (adulterated) or one that misleads consumers. Consumers would be misled if, for example, the additive makes a product "appear to be a better value than it actually is or it masks spoilage," says Post.

The FSIS evaluated data submitted by the petitioner to ensure suitability for a number of ready-to-eat products, such as sausages, turkey, soups, stews, hot dogs, bologna, Vienna sausage, and cooked ham and turkey.

Labeling

Under the Federal Meat Inspection Act and the Poultry Products Inspection Act, both administered by the USDA, the use of the phage preparation must be declared on labeling as an ingredient. Consumers will see "bacteriophage preparation" on the label of meat or poultry products that have been treated with the food additive.

If consumers have any concerns about what they're getting at the deli counter, says Post, "they always have the ability to ask for the label of the product being prepared or sliced to see what it contains."

A Phage First

This approval marks the first time that the FDA has regulated the use of a phage preparation as a food additive. Phages are currently approved in the United States for pesticide applications, such as spraying on crops.

Scientists continue to be interested in other uses for phages, such as to prevent food products from contamination with other types of harmful bacteria and to act as possible treatments for bacterial infections in people.

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For More Information

FDA Bacteriophage Questions and Answers

EPA 1494

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U. S. Food and Drug Administration
FDA/IFIC Brochure: January 1992

(This document also available in other languages.)

Food Additives

Q.What keeps bread mold-free and salad dressings from separating?

Q. What helps cake batters rise reliably during baking and keeps cured meats safe to eat?

Q. What improves the nutritional value of biscuits and pasta, and gives gingerbread its distinctive flavor?

Q.What gives margarine its pleasing yellow color and prevents salt from becoming lumpy in its shaker?

Q. What allows many foods to be available year-round, in great quantity and the best quality?

A. FOOD ADDITIVES

Food additives play a vital role in today's bountiful and nutritious food supply. They allow our growing urban population to enjoy a variety of safe, wholesome and tasty foods year-round. And, they make possible an array of convenience foods without the inconvenience of daily shopping.

Although salt, baking soda, vanilla and yeast are commonly used in foods today, many people tend to think of any additive added to foods as complex chemical compounds. All food additives are carefully regulated by federal authorities and various international organizations to ensure that foods are safe to eat and are accurately labeled. The purpose of this brochure is to provide helpful background information about food additives, why they are used in foods and how regulations govern their safe use in the food supply.

Why are Additives Used in Foods?

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Additives perform a variety of useful functions in foods that are often taken for granted. Since most people no longer live on farms, additives help keep food wholesome and appealing while en route to markets sometimes thousands of miles away from where it is grown or manufactured. Additives also improve the nutritional value of certain foods and can make them more appealing by improving their taste, texture, consistency or color.

Some additives could be eliminated if we were willing to grow our own food, harvest and grind it, spend many hours cooking and canning, or accept increased risks of food spoilage. But most people today have come to rely on the many technological, aesthetic and convenience benefits that additives provide in food.

Additives are used in foods for five main reasons:

- To Maintain product consistency. Emulsifiers give products a consistent texture and prevent them from separating. Stabilizers and thickeners give smooth uniform texture. Anti-caking agents help substances such as salt to flow freely.

- To improve or maintain nutritional value. Vitamins and minerals are added to many common foods such as milk, flour, cereal and margarine to make up for those likely to be lacking in a person's diet or lost in processing. Such fortification and enrichment has helped reduce malnutrition among the U.S. population. All products containing added nutrients must be appropriately labeled.

- To maintain palatability and wholesomeness. Preservatives retard product spoilage caused by mold, air, bacteria, fungi or yeast. Bacterial contamination can cause foodborne illness, including life-threatening botulism. Antioxidants are preservatives that prevent fats and oils in baked goods and other foods from becoming rancid or developing an off-flavor. They also prevent cut fresh fruits such as apples from turning brown when exposed to air.

- To provide leavening or control acidity/alkalinity. Leavening agents that release acids when heated can react with baking soda to help cakes, biscuits and other baked goods to rise during baking. Other additives help modify the acidity and alkalinity of foods for proper flavor, taste and color.

- To enhance flavor or impart desired color. Many spices and natural and synthetic flavors enhance the taste of foods. Colors, likewise, enhance the appearance of certain foods to meet consumer expectations. Examples of substances that perform each of these functions are provided in the chart "Common Uses of Additives."

Many substances added to food may seem foreign when listed on the ingredient label, but are actually quite familiar. For example, ascorbic acid is another name for Vitamin C; alphatocopherol is another name for Vitamin E; and beta-carotene is a source of Vitamin A. Although there are no easy synonyms for all additives, it is helpful to remember that

all food is made up of chemicals. Carbon, hydrogen and other chemical elements provide the basic building blocks for everything in life.

What is a Food Additive?

In its broadest sense, a food additive is any substance added to food. Legally, the term refers to "any substance the intended use which results or may reasonably be expected to result-directly or indirectly-in its becoming a component or otherwise affecting the characteristics of any food." This definition includes any substance used in the production, processing, treatment, packaging, transportation or storage of food.

If a substance is added to a food for a specific purpose in that food, it is referred to as a direct additive. For example, the low-calorie sweetener aspartame, which is used in beverages, puddings, yogurt, chewing gum and other foods, is considered a direct additive. Many direct additives are identified on the ingredient label of foods.

Indirect food additives are those that become part of the food in trace amounts due to its packaging, storage or other handling. For instance, minute amounts of packaging substances may find their way into foods during storage. Food packaging manufacturers must prove to the U.S. Food and Drug Administration (FDA) that all materials coming in contact with food are safe, before they are permitted for use in such a manner.

What is a Color Additive?

A color additive is any dye, pigment or substance that can impart color when added or applied to a food, drug, or cosmetic, or to the human body. Color additives may be used in foods, drugs, cosmetics, and certain medical devices such as contact lenses. Color additives are used in foods for many reasons, including to offset color loss due to storage or processing of foods and to correct natural variations in food color.

Colors permitted for use in foods are classified as certified or exempt from certification. Certified colors are man-made, with each batch being tested by the manufacturer and FDA to ensure that they meet strict specifications for purity. There are nine certified colors approved for use in the United States. One example is FD&C Yellow No.6, which is used in cereals, bakery goods, snack foods and other foods.

Color additives that are exempt from certification include pigments derived from natural sources such as vegetables, minerals or animals. For example, caramel color is produced commercially by heating sugar and other carbohydrates under strictly controlled conditions for use in sauces, gravies, soft drinks, baked goods and other foods. Most colors exempt from certification also must meet certain legal criteria for specifications and purity.

How are Additives Regulated?

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Additives are not always byproducts of 20th century technology or modern know-how. Our ancestors used salt to preserve meats and fish; added herbs and spices to improve the flavor of foods; preserved fruit with sugar; and pickled cucumbers in a vinegar solution.

Over the years, however, improvements have been made in increasing the efficiency and ensuring the safety of all additives. Today food and color additives are more strictly regulated that at any other time in history. The basis of modern food law is the Federal Food, Drug, and Cosmetic (FD&C) Act of 1938, which gives the Food and Drug Administration (FDA) authority over food and food ingredients and defines requirements for truthful labeling of ingredients.

The Food Additives Amendment to the FD&C Act, passed in 1958, requires FDA approval for the use of an additive prior to its inclusion in food. It also requires the manufacturer to prove an additive's safety for the ways it will be used.

The Food Additives Amendment exempted two groups of substances from the food additive regulation process. All substances that FDA or the U.S. Department of Agriculture (USDA) had determined were safe for use in specific food prior to the 1958 amendment were designated as prior-sanctioned substances. Examples of prior-sanctioned substances are sodium nitrite and potassium nitrite used to preserve luncheon meats.

A second category of substances excluded from the food additive regulation process are generally recognized as safe or GRAS substances. GRAS substances are those whose use is generally recognized by experts as safe, based on their extensive history of use in food before 1958 or based on published scientific evidence. Salt, sugar, spices, vitamins and monosodium glutamate are classified as GRAS substances, along with several hundred other substances. Manufacturers may also request FDA to review the use of a substance to determine if it is GRAS.

Since 1958, FDA and USDA have continued to monitor all prior sanctioned and GRAS substances in light of new scientific information. If new evidence suggests that a GRAS or prior sanctioned substance may be unsafe, federal authorities can prohibit its use or require further studies to determine its safety.

In 1960, Congress passed similar legislation governing color additives. The Color Additives Amendments to the FD&C Act require dyes used in foods, drugs, cosmetics and certain medical devices to be approved by FDA prior to their marketing.

In contrast to food additives, colors in use before the legislation were allowed continues use only if they underwent further testing to confirm their safety. Of the original 200 provisionally listed color additives, 90 have been listed as safe and the remainder have either been removed from use by FDA or withdrawn by industry.

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Both the Food Additives and Color Additives Amendments include a provision which prohibits the approval of an additive if it is found to cause cancer in humans or animals. This clause is often referred to as the Delaney Clause, named for its Congressional sponsor, Rep. James Delaney (D-N.Y.).

Regulations known as Good Manufacturing Practices (GMP) limit the amount of food and color additives used in foods. Manufacturers use only the amount of an additive necessary to achieve the desired effect.

How Are Additives Approved for Use in Foods?

To market a new food or color additive, a manufacturer must first petition FDA for its approval. Approximately 100 new food and color additives petitions are submitted to FDA annually. Most of these petitions are for indirect additives such as packaging materials.

A food or color additive petition must provide convincing evidence that the proposed additive performs as it is intended. Animal studies using large doses of the additive for long periods are often necessary to show that the substance would not cause harmful effects at expected levels of human consumption. Studies of the additive in humans also may be submitted to FDA.

In deciding whether an additive should be approved, the agency considers the composition and properties of the substance, the amount likely to be consumed, its probable long-term effects and various safety factors. Absolute safety of any substance can never be proven. Therefore, FDA must determine if the additive is safe under the proposed conditions of use, based on the best scientific knowledge available.

If an additive is approved, FDA issues regulations that may include the types of foods in which it can be used, the maximum amounts to be used, and how it should be identified on food labels. Additives proposed for use in meat and poultry products also must receive specific authorization by USDA. Federal officials then carefully monitor the extent of Americans' consumption of the new additive and results of any new research on its safety to assure its use continues to be within safe limits.

In addition, FDA operates an Adverse Reaction Monitoring System (ARMS) to help serve as an ongoing safety check of all additives. The system monitors and investigates all complaints by individuals or their physicians that are believed to be related to specific foods; food and color additives; or vitamin and mineral supplements. The ARMS computerized database helps officials decide whether reported adverse reactions represent a real public health hazard associated with food, so that appropriate action can be taken.

Summary

Additives have been used for many years to preserve, flavor, blend, thicken and color foods, and have played an important role in reducing serious nutritional deficiencies among Americans. Additives help assure the availability of wholesome, appetizing and affordable foods that meet consumer demands from season to season.

Today, food and color additives are more strictly regulated that at any time in history. Federal regulations require evidence that each substance is safe at its intended levels of use before it may be added to foods. All additives are subject to ongoing safety review as scientific understanding and methods of testing continue to improve.

Additional Information About Additives

Q. What is the difference between "natural" and "artificial" additives?

A. Some additives are manufactured from natural sources such as soybeans and corn, which provide lecithin to maintain product consistency, or beets, which provide beet powder used as food coloring. Other useful additives are not found in nature and must be man-made. Artificial additives can be produced more economically, with greater purity and more consistent quality than some of their natural counterparts. Whether an additive is natural or artificial has no bearing on its safety.

Q. Is a natural additive safer because it is chemical-free?

A. No. All foods, whether picked from your garden or your supermarket shelf, are made up of chemicals. For example, the vitamin C or ascorbic acid found in an orange is identical to that produced in a laboratory. Indeed, all things in the world consist of the chemical building blocks of carbon, hydrogen, nitrogen, oxygen and other elements. These elements are combined in various ways to produce starches, proteins, fats, water and vitamins found in foods.

Q. Are sulfites safe?

A. Sulfites added to baked goods, condiments, snack foods and other products are safe for most people. A small segment of the population, however, has been found to develop hives, nausea, diarrhea, shortness of breath or even fatal shock after consuming sulfites. For that reason, in 1986 FDA banned the use of sulfites on fresh fruits and vegetables intended to be sold or served raw to consumers. Sulfites added as a preservative in all other packaged and processed foods must be listed on the product label.

Q. Does FD&C Yellow No.5 cause allergic reactions?

A. FD&C Yellow No.5, or tartrazine, is used to color beverages, desert powders, candy ice cream, custards and other foods. The color additive may cause hives in fewer than one out of 10,000 people. By law, whenever the color is added to foods or taken internally, it

must be listed on the label. This allows the small portion of people who may be sensitive to FD&C Yellow No.5 to avoid it.

Q. Does the low calorie sweetener aspartame carry adverse reactions?

A. There is no scientific evidence that aspartame causes adverse reactions in people. All consumer complaints related to the sweetener have been investigated as thoroughly as possible by federal authorities for more than five years, in part under FDA's Adverse Reaction Monitoring System. In addition, scientific studies conducted during aspartame's pre-approval phase failed to show that it causes any adverse reactions in adults or children. Individuals who have concerns about possible adverse reactions to aspartame or other substances should contact their physicians.

Q. Do additives cause childhood hyperactivity?

A. No. Although this theory was popularized in the 1970's, well-controlled studies conducted since that time have produced no evidence that food additives cause hyperactivity or learning disabilities in children. A Consensus Development Panel of the National Institutes of Health concluded in 1982 that there was no scientific evidence to support the claim that additives or colorings cause hyperactivity.

Q. Why are decisions sometimes changed about the safety of food ingredients?

A. Since absolute safety of any substance can never be proven, decisions about the safety of food ingredients are made on the best scientific evidence available. Scientific knowledge is constantly evolving. Therefore, federal officials often review earlier decisions to assure that the safety assessment of a food substance remains up to date. Any change made in previous clearances should be recognized as an assurance that the latest and best scientific knowledge is being applied to enhance the safety of the food supply.

Q. What are some other food additives that may be used in the future?

A. Among other petitions, FDA is carefully evaluating requests to use ingredients that would replace either sugar or fat in food. In 1990, FDA confirmed the GRAS status of Simplesse, (registered trademark) a fat replacement made from milk or egg white protein, for use in frozen desserts. The agency also is evaluating a food additive petition for olestra, which would partially replace the fat in oils and shortenings.

Q. What is the role of modern technology in producing food additives?

A. Many new techniques are being researched that will allow the production of additives in ways not previously possible. One approach, known as biotechnology, uses simple organisms to produce additives that are the same food components found in nature. In 1990, FDA approved the first bioengineered enzyme, rennin, which traditionally has been

extracted from calves' stomachs for use in making cheese.

Common Uses of Additives

*Additive Functions/Examples**	*Foods Where Likely Used*
Impart/Maintained Desired Consistency	
Alginates, Lecithin, Mono-& Diglycerides, Methyl Cellulose, Carrageenan, Glyceride, Pectin, Guar Gum, Sodium Aluminosilicate	Baked Goods, Cake Mixes, Salad dressings, Ice cream, Process Cheese, Coconut, Table Salt
Improve/Maintain Nutritive Value	
Vitamins A and D, Thiamine, Niacin, Riboflavin, Pyridoxine, Folic Acid, Ascorbic Acid, Calcium Carbonate, Zinc Oxide, Iron	Flour, Bread, Biscuits, Breakfast Cereals, Pasta, Margarine, Milk, Iodized Salt, Gelatin Desserts
Maintain Palatability and Wholesomeness	
Propionic Acid & its Salts, Ascorbic Acid, Butylated Hydroxy anisole (BHA), Butylated Hydroxytoluene (BHT), Benzoates, Sodium Nitrite, Citric Acid	Bread, Cheese, Crackers, Frozen & Dried Fruit, Margarine, Lard, Potato Chips, Cake Mixes, Meat
Produce Light Texture; Control Acidity/Alkalinity	
Yeast, Sodium Bicarbonate, Citric Acid, Fumaric Acid, Phosphoric Acid, Lactic Acid, Tartrates	Cakes, Cookies, Quick Breads, Crackers, Butter, Chocolates, Soft Drinks
Enhance Flavor or Impart Desired Color	
Cloves, Ginger, Fructose, Aspartame, Saccharin, FD&C Red No.40, Monosodium Glutamate, Caramel, Annatto, Limonene, Turmeric	Spice Cake, Gingerbread, Soft Drinks, Yogurt, Soup, Confections, Baked Goods, Cheeses, Jams,

EPA1502

Gum

*Includes GRAS and prior sanctioned substances as well as food additives.

**Food and Drug Administration/ International Food Information Council Brochure: January 1992*

Foods Home | FDA Home | HHS Home | Search/Subject Index | Disclaimers & Privacy Policy | Accessibility/Help

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EPA1503

Cx

67

Guidance on Ingredients and Sources of Radiation Used to Reduce Microorganisms on Carcasses, Ground Beef, and Beef Trimmings

Purpose

This document is intended to provide guidance to interested parties who wish to use new antimicrobial agents, e.g. organic acids and acidified sodium chlorite or to make new use of antimicrobial agents that are already employed in the production of beef carcasses, ground beef, and beef trimmings, to reduce the presence of pathogenic microorganisms on meat products. This document will provide some background information on the ingredient approval process and the different classes of approved antimicrobial agents, and then provide guidance on the labeling of these substances.

Background

All ingredients and sources of radiation must be determined to be safe and suitable before they can be used in the production of meat and poultry products. On December 23, 1999, the Food Safety and Inspection Service (FSIS) published, in the Federal Register, a final rule entitled "Food Ingredients and Sources of Radiation Listed or Approved for Use in the Production of Meat and Poultry Products." This final rule explained how the Food and Drug Administration (FDA) and FSIS will work together regarding requests for approvals of ingredients and sources of radiation to be used in or on meat and poultry products. The final rule streamlined the approval process by providing for the simultaneous review by FDA and FSIS of requests and petitions. A Memorandum of Understanding (MOU) was implemented in January 2000 that outlines the procedures for such reviews. The final rule, the MOU, and a document entitled "Guidance on the Procedures for Joint Food Safety and Inspection Service (FSIS) and Food and Drug Administration (FDA) Approval of Ingredients Used in the Production of Meat and Poultry Products," which describes the process for approving the use of ingredients in detail, may be accessed through the FSIS Labeling and Additives Policy website at: www.fsis.usda.gov/oppde/larc.

Antimicrobial Agents

Some studies show that certain ingredients provide an antimicrobial effect of reducing the levels of pathogenic microorganisms, such as *E. coli* O157:H7, *Salmonella*, and *Listeria*. Since December 1999, FSIS and FDA have worked together to evaluate and approve or list as safe and suitable food ingredients for use in the production of meat and poultry that

have an antimicrobial effect.

Classification of Antimicrobial Agents

Antimicrobial agents can have a momentary or a lasting effect in or on the treated product and, thus, are classified by the technical effect. The technical effect will determine the approval process and the labeling.

Direct Additives

FSIS and FDA regulations allow various meat and poultry products, including ground beef and trimmings, to be treated with direct food additives, e.g., Lactoferrin, a Generally Recognized as Safe (GRAS) substance. Direct food additives are considered ingredients of a product and must be included in the ingredients statement on the product's labeling. Substances are considered to be ingredient if they remain in the food product and have a lasting effect on the product. Furthermore, because, at present, the standards of identity for ground beef and trimmings are such that these are considered to be single-ingredient raw products, they are not expected by consumers to include other substances, the use of direct additives in these products must be reflected in the product's name, e.g., "Ground Beef, treated with milk-derived Lactoferrin." Comminuted beef products that do not have established regulatory food standards of identity may include these ingredients in their formulations without implications for product names.

Secondary Direct Food Additives

Acidified sodium chlorite, peroxyacids, and ozone are examples of substances that have been approved as secondary direct food additives. Secondary direct food additives provide a momentary technical effect and not a lasting effect in the treated food. These substances are ordinarily removed from the final food, and any residuals that may carry over to the final product are not expected to exhibit any technical effect. Thus, they would be considered processing aids under FDA's definition of that term in 21 CFR, 101.100(a)(3), i.e., there is no lasting functional effect, and there is an insignificant amount present in the finished product under the proposed conditions of use. Even though FSIS has no definition of "processing aid" in its labeling regulations, the Agency, through the Labeling and Consumer Protection Staff (LCPS), which serves as FSIS' focal point on the use and labeling of food ingredients, makes judgments on a case-by-case basis using FDA's definition of a processing aid to decide whether the use of a substance is as a processing aid or as an ingredient of a food. If a substance is a processing aid, it need not be declared in the ingredients statement, nor need there be provision for its use in any standard of identity that is applicable to the finished food.

The Table below reflects the currently approved substances for use in the production of meat carcasses, parts, and comminuted products for the purpose of microbial reduction.

Ingredient Name	CFR Reference/Other Reference	Products for Which Application Approved	Classification
Sodium and Potassium Lactate	9 CFR 424.21 (c)	Various meat and poultry products.	Direct food additive
Sodium Citrate buffered with citric acid to a pH 0f 5.6	Acceptability determination	Non-standardized comminuted meat and poultry products.	Direct food additive
Sodium Diacetate	9 CFR 424.21 (c)	Various meat and poultry products.	Direct food additive
Lactoferrin	GRAS Notice (FDA Website)	Beef carcasses and parts	Direct food additive
Peroxyacids (a mixture of peroxyacetic acid, octanoic acid, acetic acid, hydrogen peroxide, peroxyoctanoic acid, and 1-hydroxyethylidene-1,1-diphosphonic acid)	21 CFR 173.370	Beef carcasses	Secondary direct food additive/Processing Aid
Acidified sodium chlorite	21 CFR 173.325	Carcasses, parts, and trimmings, as well as all processed, comminuted or formed meat food products.	Secondary direct food additive/Processing Aid
Ozone	21 CFR 173.368	All meat and poultry products	Secondary direct food additive/Processing Aid
Sources of ionizing radiation	21 CFR 179.26	Pork, poultry, and beef products as listed.	Food additive

One example of how FSIS' approach works is presented by the use of organic acids. Lactic acid, acetic acid, citric acid, ascorbic acid, and other organic acids are approved or listed in FDA regulations for various technical purposes, e.g., as acidulants, antioxidants, flavoring agents, pH adjusters, nutrients, and preservatives. There may also be other uses of these organic acids by non-meat and poultry food processors for which FDA has accepted a determination by the proponent of use of the substance that the use is GRAS. For these uses, FSIS must have from FDA, at the very least, a written statement of no objection with regard to the safety of the use of the substance. The USDA mark of inspection for meat and poultry products reflects a determination by FSIS that the food product is not adulterated, and thus that all ingredients used to make the product must be safe and suitable for the product to receive the mark.

FSIS has specifically approved lactic acid, acetic acid, and citric acid as antimicrobial agents in the final wash that is applied to livestock carcasses after trimming and inspection but before chilling. The Agency's decision about this use of organic acids was based on industry requests that were supported by data that showed that this application of organic acids meets FDA's definition a processing aid (21 CFR 101.100 (a) (3)). Therefore, products made from the organic acid-treated carcasses do not have to declare the organic acids in the ingredients statement on the product label.

Organic acids have also been approved for use in various meat food products for certain technical effects (e.g., as acidulants to adjust pH, flavoring agents, and color preservatives). These uses are listed in the table of approved substances in 9 CFR 424.21 (c). When organic acids are used for the purposes indicated in the table, they are considered to be ingredients of the product since they are in the finished meat food product at a detectable level, and they exhibit a continuing technical effect in or on the meat food product. Therefore, the organic acids must be declared on the label of the meat food product.

If a company is interested in using one or more of these organic acids as an antimicrobial agent on beef trim (i.e., a post-chill application) and does not want to declare the acid in the ingredients statement on the label of the meat food product, they must provide data to LCPS that show that the use complies with FDA's definition of a processing aid. The data must show that the acid is not having a continuing effect on the meat food product. Specifically, the supporting data must show that the fresh color of the meat is not preserved. The product will exhibit normal spoilage indicators (e.g., discoloration); and that there is no extension of shelf life as compared to products made from untreated trimmings. The data must also show that the nutrient composition is not affected by the treatment, e.g., protein is not denatured, and vitamins are not enhanced. The data must address the sensory characteristics (i.e., color and odor) of the product and show that the characteristics are not altered as compared to untreated trim. Finally, there must not be any detectable residues of the organic acid in the meat food product derived from the treated trim.

EPA1507

Occasionally, processors request consideration of the use of ingredients without the need for labeling them on products, e.g., the treatment of meat cuts and ground beef with organic acids. To date, no data have been submitted to LCPS to show that post-chiller applications of these organic acids to carcasses, parts or trimmings are situations that are consistent with FDA's labeling definition of a processing aid. Therefore, these substances would be considered ingredients that are direct food additives when used in this way, and their use in ground beef and trimmings derived from trimmings treated post-chiller would need to be identified on product labeling.

Additional Information

Additional guidance on the use and labeling of ingredients and sources of radiation for use in meat and poultry may be obtained from LCPS at www.fsis.usda.gov/oppde/larc or at (202) 205-0279.

[Return to Related Documents]

Cx68

FDA U.S. Food and Drug Administration Department of Health and Human Services
CENTER FOR FOOD SAFETY AND APPLIED NUTRITION

CFSAN/Office of Food Additive Safety
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Food Ingredients and Packaging Terms

The Food and Drug Administration (FDA) Data Standards Council is standardizing vocabulary across the FDA. Therefore, the wording in some terms below may change slightly in the future.

Biotechnology - refers to techniques used by scientists to modify deoxyribonucleic acid (DNA) or the genetic material of a microorganism, plant, or animal in order to achieve a desired trait. In the case of foods, genetically engineered plant foods are produced from crops whose genetic makeup has been altered through a process called recombinant DNA, or gene splicing, to give the plant desired traits. Genetically engineered foods are also known as biotech, bioengineered, and genetically modified, although "genetically modified" can also refer to foods from plants altered through methods such as conventional breeding. While in a broad sense biotechnology refers to technological applications of biology, common use in the U.S. has narrowed the definition to foods produced using recombinant DNA. For additional information, see the Biotechnology Program on the CFSAN Internet.

CEDI/ADI Database - For a large number of food contact substances, CFSAN maintains a database of Cumulative Estimated Daily Intakes (CEDIs) and Acceptable Daily Intakes (ADIs). The CEDIs and ADIs are based on currently available information and may be revised when information is submitted or made available. The CEDI/ADI database is updated approximately twice annually. The CEDIs and ADIs are based on currently available information and may be subject to revision on the basis of new information as it is submitted or made available to OFAS.

Color Additive - A color additive is a dye, pigment or other substance, which is capable of imparting color when added or applied to a food, drug,

EPA1509

cosmetic, or to the human body. The legal definition can be found in Section 201 (t) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) and provides exclusions as well. Color additives for use in food, drugs, and cosmetics require premarket approval. Color additives for use in or on a medical device are subject to premarket approval, if the color additive comes in direct contact with the body for a significant period of time. For additional information, consult the Color Additive Program on the CFSAN Internet.

Colorant - A colorant is a dye, pigment, or other substance that is used to impart color to or to alter the color of a food-contact material, but that does not migrate to food in amounts that will contribute to that food any color apparent to the naked eye. The term 'colorant' includes substances such as optical brighteners and fluorescent whiteners, which may not themselves be colored, but whose use is intended to affect the color of a food-contact material. (21 CFR 178.3297(a)).

EAFUS - The "Everything Added to Food in the United States" (EAFUS) database is an informational database maintained by CFSAN under an ongoing program known as the Priority-based Assessment of Food Additives (PAFA). PAFA contains administrative, chemical and toxicological information on over 2000 substances directly added to food, including substances regulated by the FDA as a direct food additive, secondary direct food additive, color additive, GRAS and prior-sanctioned substance. In addition, the database contains only administrative and chemical information on approximately 1000 such substances. Information about the more than 3000 total substances comprise EAFUS. For a complete listing of EAFUS substances, see the EAFUS list.

Food Additive - A food additive is defined in Section 201(s) of the FD&C Act as any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristic of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use); if such substance is not GRAS or sanctioned prior to 1958[1] or otherwise excluded from the definition of food additives.

Food Contact Substance (FCS) - Section 409 of the FD&C Act defines an FCS as any substance that is intended for use as a component of materials used in manufacturing, packing, packaging, transporting, or holding food if such use of the substance is not intended to have any technical effect in such food. Additional information can be found on the Food Contact Substances

EPA1510

Notification Program page.

There is a hierarchy from **Food Contact Substance** (FCS) through Food Contact Material (FCM) to Food Contact Article (FCA).

- The **Food Contact Substance** (the subject of an FCN) is a single substance, such as a polymer or an antioxidant in a polymer. As a substance, it is reasonably pure (the Chemist's definition of substance). Even though a polymer may be composed of several monomers, it still has a well-defined composition.
- **Food Contact Material** (FCM) is made with the FCS and (usually) other substances. It is often (but not necessarily) a mixture, such as an antioxidant in a polymer. The composition may be variable.
- The **Food Contact Article** is the finished film, bottle, dough hook, tray, or whatever that is formed out of the FCM.

GRAS - "GRAS" is an acronym for the phrase Generally Recognized As Safe. Under sections 201(s) and 409 of the FD&C Act, any substance that is intentionally added to food is a food additive, that is subject to premarket review and approval by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excluded from the definition of a food additive. GRAS substances are distinguished from food additives by the type of information that supports the GRAS determination, that it is publicly available and generally accepted by the scientific community, but should be the same quantity and quality of information that would support the safety of a food additive. Additional information on GRAS can be found on the GRAS Notification Program page.

Guidance Document - Guidance documents are documents prepared for FDA staff, applicants/sponsors, and the public that describe the agency's interpretation of or policy on a regulatory issue. Guidance documents include, but are not limited to, documents that relate to the design, production, labeling, promotion, manufacturing, and testing of regulated products; the processing, content, and evaluation or approval of submissions; and inspection and enforcement policies. Guidance documents do not legally bind the public or FDA or establish legally enforceable rights or responsibilities. They represent the agency's current thinking. (21 CFR 10.115). A complete listing of CFSAN's guidance documents is available on the Internet.

EPA1511

Indirect Food Additive - In general, these are food additives that come into contact with food as part of packaging, holding, or processing, but are not intended to be added directly to, become a component, or have a technical effect in or on the food. Indirect food additives mentioned in Title 21 of the U.S. Code of Federal Regulations (21CFR) used in food-contact articles, include adhesives and components of coatings (Part 175), paper and paperboard components (Part 176), polymers (Part 177), and adjuvants and production aids (Part 178). Currently, additional indirect food additives are authorized through the food contact notification program. In addition, indirect food additives may be authorized through 21 CFR 170.39.

PAFA - The Priority based Assessment of Food Additive (PAFA) database is a database that serves as CFSAN's institutional memory for the toxicological effects of food ingredients known to be used in the United States. Currently, PAFA contains oral toxicology information on over 2100 of approximately 3300 direct food ingredients used in food in the US. PAFA also contains minimal information on over 3200 indirect additives including the names, CAS number and regulatory information of the indirect additives in the Code of Federal Regulations. The EAFUS list and the Indirect Additive list on the CFSAN Internet consist of selected fields of information generated from PAFA.

Prior Sanctioned Substance - A substance whose use in or on food is the subject of a letter issued by FDA or USDA offering no objection to a specific use. The prior sanction exists only for a specific use of a substance in food delineating level(s), condition(s) and product(s) set forth by explicit approval by FDA or USDA prior to September 6, 1958. Some prior sanctioned substances are codified in 21 CFR Part 181.

SCOGS Report - "SCOGS" is the acronym for the Select Committee On GRAS Substances. Beginning in 1972, under a contract with FDA, the Life Sciences Research Office of the Federation of American Societies for Experimental Biology convened the Select Committee, which independently undertook a comprehensive review of the safety and health aspects of GRAS food substances on the FDA's then proposed GRAS list. The Select Committee published its evaluations in a series of reports known as the SCOGS Reports. A listing of opinions and conclusions from 115 SCOGS reports published between 1972 and 1980 is available on the CFSAN Internet.

Secondary Direct Food Additive - This term is in the title of 21 CFR 173, which was created during recodification of the food additive regulations

in 1977. A secondary direct food additive has a technical effect in food during processing but not in the finished food (e.g., processing aid). Some secondary direct food additives also meet the definition of a food contact substance. For more on food contact substances, consult the Food Contact Substance Notification Program.

Threshold of Regulation (TOR) Exemption - A substance used in a food contact article may be exempted from the requirement of a food additive listing regulation if the use in question has been shown to meet the requirements in 21 CFR 170.39. For details, see 21 CFR 170.39. For a complete listing of the TOR exemptions, consult the Threshold of Regulation inventory on the CFSAN Internet.

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[1]This is a shortened definition. The full definition, found in the FD&C Act provides for additional exclusions.

Food Ingredients and Packaging

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EPA1513